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10/588,609	08/07/2006	Hisakazu Katsuki	KATSUKI=2	8366

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/588,609
Filing Date: August 07, 2006
Appellant(s): KATSUKI ET AL.

Anne M. Kornbau
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on 3/22/11 appealing from the Office action mailed 12/29/2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

Examiner is not aware of any related Appeals and Interferences.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 10, 12-14, 17 and 18 are rejected (final Rejection). Claims 10, 12-14 and 17-19 are pending. Claim 19 was added on 03/25/10 after final rejection (12/29/10) and was not entered (advisory action mailed on 04/02/10). Claims 1-9, 11, 15 and 16 are cancelled.

(4) Status of Amendments after Final

The examiner disagrees with the comments on the appellant's statement of the status of amendments after final rejection contained in the brief. Claims 10, 12-14, 17 and 18 were under final rejection and should be on appeal.

Claim 19 was added after the final action was not entered and not examined See (advisory action #3). Therefore, claim 19 was not addressed in any of the rejections. There is an inadvertent typing error in section 7 of advisory where claim 19 has been included in rejected claims and shown to be rejected however, # 7 is not checked. The examiner noted a typographical error in the "status of claims" in the appeal brief page 3 wherein Appellants stated that the rejected claims are 10, 12-1 and 17-19, while it should be "12-14".

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. 35 U.S.C. 112, second paragraph and written description rejections on claims 12 and 13 are withdrawn for "generation" and "under shading" because claims are amended and explained.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

4,666,634	Miyamoto et al.	5-1987
6,448,421	Yamauchi et al.	9-2002
WO 03/047595	Chen et al.	6-2003
JP05-004925 (Translation)	Tadahiko et al.	01-1993
JP06-087750 (Translation)	Madoka et al.	03-1994

Katsushito Miyamoto et al., (Chem Pharm. Bull. 41(6) 1111-1113, 1993).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 18 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Claim 18 contains "new matter". There is no method for "improvement" in the disclosure.

Applicant had no possession of the claimed subject matter. Specification contains no example, description, teaching or guidance so that one skilled in the art to make and use the invention as has been presently claimed.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him. See *Genetech*, 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

Applicant is kindly requested to explain the issue. See MPEP 2163.06

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. In claim 18 it is unclear what the "improvement" is?

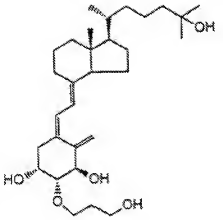
Claim Rejections - 35 USC § 102-1st Rejection

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10, 14, 17 and 18 rejected under 35 U.S.C. 102(b) as being anticipated by YAMAUCHI, Tsuyoshi (US 6,448,421). The reference discloses preparation and purification of ED-71 which anticipates Applicant's claimed invention. The reference discloses the preparation of ED-71 of formula I and tachysterol of formula III and in column 4.



6. The reference further discloses that these compounds are contained in reaction mixture obtained by ultraviolet light radiation and the subsequent thermal isomerization reaction of the pro-form of ED-71. See lines 15-19 in column 5. See the abstract also compound IX which is ED-71 in column 8. See also examples 1 and 2 where the synthesis of ED-71 has been described and pro-form and perform of ED-71 are disclosed.

7. The reference also discloses that that the tachy and lumi forms which are analogues of ED-71 and pro-form of ED-71, respectively, are novel compounds and are useful **for a test or analysis which may be carried out in the synthesis of a vitamin D derivative**. See lines 37-41 in column 19 See tables 1-5 in column 17-19 where the products are disclosed.

8. Therefore it is evident that the reference discloses all the degradation products as has been claimed. Further, the composition and all the claimed invention is **directly or inherently** disclosed by the reference.

Claims 10, 14, 17 and 18 rejected under 35 U.S.C. 102(b) as anticipated by MIYOMOTO (Chem. Pharm. Bull) and MIYAMOTO et al. (US Patent 4,666,634). The presently claimed invention is inherently disclosed by the references as follows:

MIYOMOTO (Chem. Pharm. Bull) teaches preparation of vitamin D compounds including ED-71. Various steps and intermediates are taught. See chart 2 on page 1111, experimental section on pages 1112 and 1113 are taught.

MYOMOTO in US '634 teach synthesis of ED 71, see the entire document especially example 13 and process for preparing compound and intermediates. See columns 4-9 where intermediates and ED-71 were prepared.

The references cited above inherently disclose presently claimed invention for the reasons cited above.

35 USC § 103(a) Obviousness Rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 12-14, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over YAMAUCHI, Tsuyoshi (US 6,448,421). MIYAMOTO et al. (US Patent 4,666,634 and MIYOMOTO, Chem. Pharm. Bull), JP Publication number: 05-004925, Publication Number: 06-087750 and CHEN et al. (WO 03/047595).

9. YAMAUCHI teaches the preparation of ED-71 of formula I and tachysterol of formula III and in column 4. The reference further discloses that these compounds are contained in reaction mixture obtained by ultraviolet light radiation and the subsequent thermal isomerization reaction of the pro-form of ED_71. See lines 15-19 in column 5. See also compound IX which is ED-71 in column 8. See also examples 1 and 2 where the synthesis of ED-71 has been described and pro-form and perform of ED-71 are disclosed.

10. The reference also teaches that that the tachy and lumi forms which are analogues of ED-71 and pro-form of ED-71 which is tachy form of ED-71, respectively, are novel compounds and

are useful **for a test or analysis which may be carried out in the synthesis of a vitamin D derivative**. See lines 37-41 in column 19 See tables 1-5 in column 17-19 where the products are disclosed.

11. The reference discloses all the degradation products as has been claimed. Further, the composition and all the claimed invention is taught by the reference.

MIYOMOTO (Chem. Pharm. Bull) teaches preparation of vitamin D compounds including ED-71. Various steps and intermediates are taught. See chart 2 on page 1111, experimental section on pages 1112 and 1113 are taught. MYOMOTO in US '634 teach synthesis of ED 71, see the entire document especially example 13 and process for preparing compound and intermediates. See columns 4-9 where intermediates and ED-71 were prepared.

CHEN et al teaches pharmaceutical compositions comprising an active vitamin D compound in emulsion pre-concentrate formulations, as well as emulsions and sub-micron droplet emulsions produced therefrom. The compositions comprise a lipophilic phase component, one or more surfactants, and an active vitamin D compound. The compositions may optionally further comprises a hydrophilic phase component. See the entire document especially [0056] where antioxidant BHA, BHT and **tocopherol** are taught. See [0036] and [0037] where fish oil, vegetable oils triglyceride are taught. The reference teaches active vitamin D compounds [0055] including calcitriol where antioxidants are used. The reference teaches antioxidants such as ascorbyl palmitate, butyl hydroxyl anisole (BHA), butyl hydroxyl toluene (BHT) and tocopherols **and d-tocopherols (vitamin E)** are taught (present specification discloses all these antioxidants). For the dosage see [0060].

PATENT ABSTRACTS OF JAPAN

(11) Publication number:

05-004925

(43)Date of publication of application : 14.01.1993

The reference teaches the use of tocopherol for stability "PURPOSE: To provide a soft capsule preparation improved in the storage stability of alpha calcidiol in an extremely good state. CONSTITUTION: An alpha calcidiol soft capsule preparation comprises alpha calcidiol and a medium chain aliphatic trig1yceride solution received in a gelatin Shell containing titanium

oxide and glycerol, the medium chain aliphatic triglyceride solution containing dibutylhydroxytoluene and dl-a-tocopherol in a weight ratio of 1:1 in a total weight of at least 0.005 wt.%".

PATENT ABSTRACTS OF JAPAN

(11) Publication number:

06-087750

KAWASE YASUKO

(54) MEDICINE COMPOSITION

(57) Abstract:

The reference teaches that by adding tocopherol as a stabilizer vitamin D as an active agent can be prevented from decomposing and maintain stability. "PURPOSE: To obtain a medicine composition useful for treating osteoporosis, vitamin D dysbolism, chronic renal insufficiency, etc., comprising la, 25- dihydroxycholecalciferol and a tocopherol.

CONSTITUTION: A medicine composition comprises 0.00001-0.001wt.% 1a,25-dihydroxycholecalciferol and 0.01-5wt.% tocopherol. The medicine composition is properly mixed with various additives useful for pharmaceutical preparation of common medicines such as crystalline cellulose, lactose, starch, mannitol, silicic anhydride, hydroxypropyl cellulose, magnesium stearate and anhydrous ethanol and pharmaceutically manufactured. The medicine composition can pharmaceutically be manufactured into a dosage form such as tablet, granule, fine granule or capsule. By addition of a tocopherol as a stabilizer, 1a,25-dihydroxycholecalciferol as an active ingredient can be prevented from decomposing and maintained stability"..

See both 5E, 7E and 5Z, 7E are known. The structures are disclosed as follows.

104121-92-8 REGISTRY

CN 1,3-Cyclohexanediol, 2-(3-hydroxypropoxy)-4-methylene-5-[(2E)-2-[(1R,3aS,7aR)-octahydro-1-[(1R)-5-hydroxy-1,5-dimethylhexyl]-7a-methyl-4H-inden-4-ylidene]ethylidene]-, (1R,2R,3R,5Z)- (CA INDEX NAME)

OTHER CA INDEX NAMES:

CN 9,10-Secocholesta-5,7,10(19)-triene-1,3,25-triol, 2-(3-hydroxypropoxy)-,

(1α,2β,3β,5Z,7E)- (9CI)

OTHER NAMES:

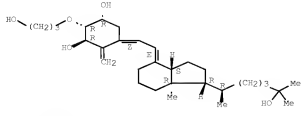
CN 2β-(3-Hydroxypropoxy)-1α,25-dihydroxyvitamin D3

CN ED 71

CN Eldecalcitol

Absolute stereochemistry. Rotation (+).

Double bond geometry as shown.



RN 861996-34-1 REGISTRY

ED Entered STN: 29 Aug 2005

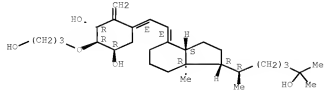
CN 9,10-Secocholesta-5,7,10(19)-triene-1,3,25-triol, 2-(3-hydroxypropoxy)-,

(1α,2β,3β,5E,7E)- (9CI) (CA INDEX NAME)

FS STEREOSEARCH

Absolute stereochemistry.

Double bond geometry as shown.



It would have been obvious to one skilled in the art to prepare additional beneficial preparation containing ED-71 and its intermediates or degradation products by using the ingredients, fat and oil and an antioxidant alpha tocopherol because all the compounds as claimed are taught by the references and use of tocopherol as good stabilizer has been taught by the JP abstracts. The degradation product would be present in composition containing ED-71. Prior art teach the degradation product.

Motivation has been provided by the prior art to prepare composition of active vitamin D compounds such as calcitriol and ED-71. Motivation to combine the teachings of CHEN, JP abstracts and MYOMOTO would have been obvious at the time of invention was filed. Even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau,* 57 USPQ 324; *Ex parte Douros,* 163 USPQ 667; and *In re Craige,* 89 USPQ 393.

The discovery of a new action underlying a known process does not make it patentable. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. Also, it is irrelevant that the prior art observers did not recognize the property or function of the disputed claim; if the prior art inherently possessed that characteristic, it anticipates. See *Verdeegal Brothers, Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 633, 2 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 1987). This is believed to be applicable here because anticipation is the epitome of obviousness.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

(10) Response to Argument

I. **Written Description Rejection**

Appellant argues that it was agreed to "formation" for "generation" and "shading" means "in absence of light". Appellant argues that under shading means "in absence of light". Examiner disagrees because under shading can be under a roof to protect from direct sunlight and not protected from any light (in absence of light). In the interview summary and advisory action examiner clearly says that "rejection under 112 will be partly withdrawn because the term "generation" has been amended to "formation" in condition that Appellant will explain where is the support of this amendment. There was no agreement on record for "shading" taken as "in absence of light" or the support for "improvement" in the interview or such a statement was given in the advisory action.

The rejection for "shading" and "generation" is withdrawn because of the amendments and explanation as discussed in the interview. Rejection over claim 18 is maintained.

Appellant argues that specification describes improvement therefore; written description rejection over claim 18 should be withdrawn.

Appellant argue that claim 18 does not contain new matter. Examiner disagrees because there is no method for "improvement" in the disclosure. Appellants are arguing that claim 18 is a Jepson claim. However no explanation has been provided.

The Jepson claims are explained in MPEP § 608.01(m)) as follows:

III. JEPSON CLAIMS

Drafting a claim in Jepson format (i.e., the format described in 37 CFR 1.75(e); see MPEP § 608.01(m)) is taken as an implied admission that the subject matter of the preamble is the prior art work of another. In re Fout, 675 F.2d 297, 301, 213 USPQ 532, 534 (CCPA 1982) (holding preamble of Jepson-type claim to be admitted prior art where applicant's specification credited another as the inventor of the subject matter of the preamble). However, this implication may be overcome where applicant gives another credible reason for drafting the claim in Jepson format. In re Ehrreich, 590 F.2d 902, 909-910, 200 USPQ 504, 510 (CCPA 1979) (holding preamble not to be admitted prior art where applicant explained that the Jepson format was used to avoid a double patenting rejection in a co-pending application and the examiner cited no art showing the subject matter of the preamble). Moreover, where the preamble of a Jepson claim describes applicant's own work, such may not be used against the claims. Reading & Bates Construction Co. v. Baker Energy Resources Corp., 748 F.2d 645, 650, 223 USPQ 1168, 1172 (Fed. Cir. 1984); Ehrreich, 590 F.2d at 909-910, 200 USPQ 200 USPQ at 510.

Appellants argues that Claim 18 which is written in the "Jepson" format, is definite and clearly states the subject matter which they regard as their invention and is in compliance with 37 C.F.R. § 1.75(e).

Examiner disagrees because The Code of Federal Regulations, Title 37 at section 1.75(e) provides:

Where the nature of the case admits, as in the case of an improvement, any independent claim should contain in the following order:

(1) A preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known,
(2) A phrase such as "wherein the improvement comprises," and
(3) Those elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved.
In present case there is no "improvement which comprises" in claim 18.

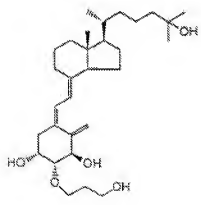
Claim Rejections - 35 USC § 112

The rejection is maintained on "improvement" in claim 18. There is no improvement for the reasons cited above.

II. Anticipation Rejection (1st Rejection)

Appellant argues that claims 10, 14, 17 and 18 are not anticipated by Yamauchi et al. (US Patent 6,448,421).

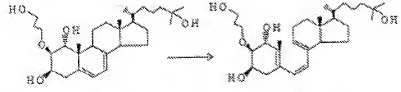
Claims 10, 14, 17 and 18 rejected under 35 U.S.C. 102(b) as being anticipated by YAMAUCHI, Tsuyoshi (US 6,448,421) because it discloses preparation and purification of ED-71 of formula I and tachysterol of formula III and in column 4.
ED-71 (column 3)



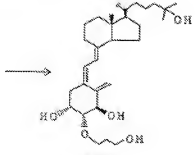
(I)

Tachy form of ED-71 is pre-form of ED-71, lines 31-37 for the spectral data, purity and identification, example 2 in column 12 for both ED-71 and tachy form which is preform).

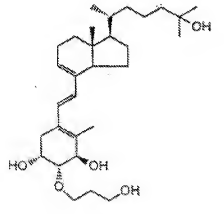
Example 2: Synthesis and purification of (1R,2R)-1,25-dihydroxy-2-(3'-hydroxypropoxy)-cholecalciferol; 2β-(3'-hydroxypropoxy)-(1α,3β,5Z,7E)-9,10-secocholesta-5,7,10(19)-triene-1,3,25-triol (ED-71)



pro form (2) pre form



ED-71



(III)

The reference further discloses that these compounds are contained in reaction mixture obtained by ultraviolet light radiation and the subsequent thermal isomerization reaction of the pro-form of ED-71 (lines 15-19 in column 5, compound IX which is ED-71 in column 8, see examples 1 and 2) where the synthesis of ED-71 has been described and pro-form and perform of ED-71 are disclosed.

12. The reference also discloses that that the tachy and lumi forms which are analogues of ED-71 and pro-form of ED-71, respectively, are novel compounds and are useful **for a test or analysis which may be carried out in the synthesis of a vitamin D derivative**. See lines 37-41 in column 19 See tables 1-5 in column 17-19 where the products are disclosed.

13. Therefore it is evident that the reference discloses the degradation products as has been claimed. Further, the composition and all the claimed invention is **directly or inherently** disclosed by the reference. Since Appellants are claiming the compositions in claim 10, the composition of mixture containing ED-71 (5Z, 7E) contains ED-71 and its tachy form which has been disclosed buy the reference. The mixture is also expected to contain ED-71 Trans form (5E, 7E) because Trans are expected to be present in the composition with stereoisomer (5Z, 7E).

14. Claim 14 is drawn to compound ED-71 which is a known compound and taught by the reference in the form of composition and is present in the composition. Claim 10 is drawn to composition. Therefore claim 14 is also anticipated. Claim 17 is drawn to Trans-form of ED-71 (5E, 7E) which is inherently taught. Claim 18 is drawn to method where the intermediate compound is 5E, 7E (transform) which is taught by the reference. Even though transform has not been mentioned it is inherently present in the composition.

II. Anticipation Rejection (2nd Rejection)

Claims 10, 14, 17 and 18 rejected under 35 U.S.C. 102(b) as anticipated by MIYOMOTO (Chem. Pharm. Bull) and MIYAMOTO et al. (US Patent 4,666,634). The presently claimed invention is inherently disclosed by the references as follows:

MIYOMOTO (Chem. Pharm. Bull) teaches preparation of vitamin D compounds including ED-71. Various steps and intermediates are taught. See chart 2 on page 1111, experimental section on pages 1112 and 1113 where the compound (e) is converted to 1alpha, 25-dihydroxy-2beta-(3-hydroxypropoxyvitamin D3 (called ED-71, 5Z, 7E) are taught. The composition is anticipated for the reasons cited above.

MYOMOTO in US '634 teach synthesis of ED 71, see the entire document especially example 13 and process for preparing compound and intermediates. See columns 4-9 where intermediates and ED-71 were prepared.

The references cited above inherently disclose presently claimed invention for the same reasons as cited above.

III. Obviousness Rejection

Appellant argues that "claims 10, 12-14, 17 and 18 are not obvious over Miyamoto Chem. Pharm. Bull., Miyamoto '634 and WO 03/047595".

Examiner notes that the rejection was made on two more JP references which are missing here in arguments.

Rejection is as follows:

Claims 10, 12-14, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over YAMAUCHI, Tsuyoshi (US 6,448,421), MIYAMOTO et al. (US Patent 4,666,634 and MIYOMOTO, Chem. Pharm. Bull), JP Publication number: 05-004925, Publication Number: 06-087750 and CHEN et al. (WO 03/047595).

The arguments are made only on Miyamoto Chem. Pharm. Bull., Miyamoto '634 and WO 03/047595. Two references are missing in the arguments.

The references teach the composition, preparation and purification of ED-71 which embraces Applicant's claimed invention.

15. JP 06-087750 teaches by the addition of the stabilizer, 1alpha, 25-dihydroxycholecalciferol can be prevented from decomposition and maintained stability. JP-05-004925 teaches the preparation of alpha calcidiol preparation of capsule with improved storage stability in an extremely good state. The reference teaches the use of antioxidants which includes dl-tocopherol.

Examiner disagree that Chen does not teach "antioxidants" because the reference teaches ascorbyl palmitate, butyl hydroxyl anisole (BHA), butyl hydroxyl toluene (BHT) and **tocopherols and d-tocopherols (vitamin E)** [see 0056] on page 16 of the reference. Present specification discloses all these antioxidants. Furthermore, the term "comprising" in claims allows other components can be added. See the entire document especially [0056] where antioxidant BHA, BHT and **tocopherol** are taught. See [0036] and [0037] where fish oil, vegetable oils triglyceride are taught. The reference teaches active vitamin D compounds [0055]

including calcitriol where antioxidants are used. The reference teaches antioxidants which includes tocopherols **and d-tocopherols (vitamin E)**. For the dosage see [0060].

The abstract of the invention as disclosed in the publication on STN further supports examiners point that the trans compounds is the degradation product and Appellants are trying to suppress the formation of this compound.

The publish abstract (DN 143:199944, CAPLUS, abstract of WO 200574943) is "Disclosed is a pharmaceutical preparation which can inhibit (5Z,7E)-(1R,2R,3R)-2-(3-hydroxypropoxy)-9,10-secocholesta-5,7,10(19)- triene-1,3,25-triol (ED-71) from yielding tachysterol and the trans isomer, which are major products of the decomposition of ED-71 during storage at room temperature.

The pharmaceutical preparation comprises (5Z,7E)-(1R,2R,3R)-2-(3- hydroxypropoxy)-9,10-secocholesta-5,7,10(19)-triene-1,3,25-triol, a fat, and an antioxidant. For example, a composition containing ED-71, ethanol 1.3, dibutylhydroxytoluene (BHT) 0.02, and medium-chain triglyceride balance to 100 % was filled in a gelatin soft capsule shell". Claim 13 of the present invention is drawn to 1R,2R)-1,25-dihydroxy-2-(3'-hydroxypropoxy)-cholecalciferol; 2.beta.-(3'-hydroxypropoxy)-(1.alpha.,3.beta.,5Z,7E)-9,10-secocholesta-5,7 ,10(19)-triene-1,3,25-triol (ED-71). See example 5: (page 34), **dl-a-tocopherol** (manufactured by Wako Pure Chemical Industries, Ltd.), dibutylhydroxytoluene (manufactured by Wako Pure Chemical Industries, Ltd.), butylhydroxyanisole (manufactured by Wako Pure Chemical Industries, Ltd.),

The trans ED-71 is a degradation product and is present in ED-71 in a very small quantity. **The preparation taught by WO reference contains all the ingredients as claimed.** Nothing new was found in the preparation of ED-71. Prior art does teach the composition which contains the products as in claim 10, 12, 13, 14 and 16.

It is important to note that Trans form of ED-71 differs from ED-71 only in the position of CH2 in the ring.

Appellants are addressing the references separated while the rejections are based on the combination of the references. It has been decided by the court that "One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references". See In re Keller, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

Furthermore, it has also been decided that "when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742

See also KSR Supreme Court of United States Decision KSR INTERNATIONAL CO. v. TELEFLEX INC. et al. No. 04-1350; 550 U.S.-, 82 USPQ 2d 1385 (2007) where it states that (1) "However, the issue is not whether a person skilled in the art had the motivation to combine the electronic control with an adjustable pedal assembly, but whether a person skilled in the art had the motivation to attach the electronic control to the support bracket of pedal assembly". (2) "the results of ordinary innovation are not the subject of exclusive rights under the patent laws". In the present case the as claimed would have been obvious to one skilled in the art at the time the invention was made.

The rejections are maintained for the same reasons as set forth in the final rejection.

Declaration

The declaration filed by Applicants on 08/20/09 and amended claim limit the antioxidant to dl-alpha-tocopherol. The declaration was fully considered but was not found persuasive. Since tocopherol has been taught by the references for example JP-Pub No. 06-087750 teaches that tocopherol is a stabilizer and is used to stabilize the composition and Chen reference also teaches tocopherol as excellent antioxidant it would have been obvious to one skilled in the art at the time the invention was filed to use tocopherol to stabilize the compositions and slow down

the degradation of the products present in the compositions. See table 1 on page 23 in CHEN where Vitamin E-TPGS shows excellent % recovery, in 14 days 103.60 % recovery at 40 C and 100.15% recovery at 60C. The results were unexpected and one would pick tocopherol in the composition to slow down any degradation and expect more recovery of the main ingredient. In present case it is vitamin D compound. Vitamin E-TPGS as used by CHEN is tocopherol polyethylene glycol succinate is good antioxidant. In method claims 12 and 13 "comprising" has been used which allows other components to be added. Appellant is trying to establish that use of tocopherol in composition is unexpected for suppressing the degradation products. Examiner believes that results as presented are not unexpected as is evidenced by the cited references especially CHEN reference for the reasons cited above. The rejection is maintained.

The corrections needed in brief as noted:

1. The references JP Publication number: 05-004925 and Publication Number: 06-087750 in obviousness rejections are missing from the arguments (VI).
2. Number of claims rejected in obviousness rejections include claim 13 as on record which is missing in Appellants arguments (VI), page 13.
3. Claim numbers are incorrect in Status of claims (page 3 of brief)). It is a typing error and should be claims 12-14 and not 12-1.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Sabiha Qazi/

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